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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/367,629 10/18/99 GUPTA

A 9403-2

023973  
DRINKER BIDDLE & REATH  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA PA 19103-6996

HM12/1106

EXAMINER
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CHAUDHRY, M

ART UNIT	PAPER NUMBER
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1623

DATE MAILED:

11/06/01

12

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/367,629

Applicant(s)

GUPTA, AJAY

Examiner

Mahreen Chaudhry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 and 48-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Status of the claims*

1. Acknowledgement is made of the amendment received August 20, 2001. Claims 44-47 have been cancelled.

The indication of allowable of subject matter in the previous office action is withdrawn in view of the following new grounds for rejection.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless :

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 36, 39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,851,985 issued to Tepic et al. Tepic et al. disclose a dialysate solution comprising water soluble vitamins including thiamine, pyridoxal and folic acid (Column 18, Lines 22-27; Column 16, Lines 49-56). Tepic et al. further disclose that the dialysate solution is utilized in a hemodialysis procedure (Column 12, Lines 58; Column 1, Lines 10-14).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-12, 19, 20, 22-28 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tepic et al. in view of U.S. Patent 5,108,767 issued to Mulchandani et al. Tepic et al. disclose a method for the delivery of supplements including water soluble vitamins in a dialysis solution in order to replace substances lost in the dialysate (Column 9, Lines 44-67). Tepic et al. further disclose that these water soluble vitamins include thiamine, pyridoxal and folic acid (Column 18, Lines 22-27; Column 16, Lines 49-56). Tepic et al. teach that supplements are included in dialysis fluid at concentrations comparable to those found in normal plasma (Column 3, Lines 51-58). Tepic et al. additionally teach that the method of supplementing the dialysis fluid may be utilized for the treatment of renal failure patients (Column 10, Lines 1+).

Tepic et al. do not expressly disclose that the supplemented dialysis solutions may be utilized to correct vitamin deficiencies in dialysis patients. However, Tepic et al. do teach that the supplemented dialysis solution are appropriate for the treatment of renal failure patients. Vitamin deficiency is known to occur in renal failure patients. Mulchandani et al. disclose that the vitamin nutritional status is compromised in renal patients and that vitamin supplementation is often required (Column 3, Lines 50+). Mulchandani et al. further disclose that supplementation of pyridoxine at an amount between 5 and 10 mg/day and folic acid at an

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amount of approximately 1 mg/day is often required (Column 3, Lines 60-65). It would therefore have been obvious to one having ordinary skill in the art to have utilized the dialysis solutions supplemented by appropriate concentrations of water soluble vitamins as taught by Tepic et al. in the treatment of vitamin deficiency in renal failure patients. A motivation for such treatment is provided by Tepic et al. who teach that supplemented dialysis fluid may be appropriate for treatment of renal failure patients.

Tepic et al. do not expressly disclose that the dialysate solution may be utilized in peritoneal dialysis. However, since Tepic et al. do teach that the supplemented dialysis solution may be utilized in the dialysis of renal failure patients and since renal failure patients are known to be treating using both hemodialysis and peritoneal dialysis, it would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized the vitamin supplemented dialysis solutions taught by Tepic et al. in the hemodialysis and peritoneal dialysis of renal failure patients in order to correct vitamin deficiencies.

6. Claims 16-18, 31-32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tepic et al. in view of Mulchandani et al. as applied to claims 1-12, 19-20, 22-28 and 33-34 above, and further in view of U.S. Patent 4,237,167 issued to Cavazza et al. The applicability of Tepic et al. and Mulchandani et al. to the instant application has been discussed above. Cavazza et al. disclose the addition of acyl-carnitine to a dialysis solution in order to supplement depleted carnitine in patients undergoing dialysis (Column 3, Lines 49-60). Cavazza et al. further teach that the dialysis solution may contain a quantity of acyl-carnitine that is equimolar to plasma carnitine or a more concentrated solution (Column 3, Lines 65+). Cavazza et al. specifically

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teach that the dialysis solution contains 50 to 100  $\mu\text{mol/L}$  of acyl-carnitine (Column 4, Lines 4-6). It would therefore have been obvious to one having ordinary skill in the art to have added carnitine as taught by Cavazza et al. to the dialysis solution taught by Tepic et al.

7. Claims 13-15, 29-30 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tepic et al. in view of Mulchandani as applied to claims 1-12, 19-20, 22-28 and 33-34 above, and further in view of Pru et al. The applicability of Tepic et al. and Mulchandani et al. to the instant application has been discussed above. Pru et al. disclose that vitamin C can be added to the dialysate in order to treat the vitamin C deficiency occurring in patients on hemodialysis (abstract). Pru et al. does not expressly disclose that vitamin C can be added to peritoneal dialysis solution; however, since patients undergoing peritoneal dialysis, like those undergoing hemodialysis, suffer from vitamin C deficiency, it would have been obvious to one having ordinary skill in the art to have added vitamin C to peritoneal dialysis solutions. Neither Pru et al. nor Tepic et al. specifically disclose that water soluble vitamins and vitamin C can be added to a dialysis solution together. However, it would have been obvious to one having ordinary skill in the art that to have added these vitamins to the dialysis solutions together since dialysis patients are known to suffer from deficiencies in various water soluble vitamins and vitamin C and doing so would allow the treatment of several vitamin deficiencies at one time. Furthermore, it would have been obvious to have added vitamin C at a concentration appropriate to treat its deficiency.

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8. Claims 21, 35, 43 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tepic et al. in view of Mulchandani et al. and further in view of both Cavazza et al. and Pru et al. The applicability of Tepic et al. and Mulchandani et al. to the instant invention has been discussed above. Cavazza et al. teach that carnitine can be added to dialysis solution in order to treat carnitine deficiency. Pru et al. teach that Vitamin C can similarly be added to a dialysis solution in order to treat vitamin C deficiency. Tepic et al. teach the addition of water soluble vitamins and folic acid to dialysis solutions in order to renal failure patients. Mulchandani et al. teach that renal failure patients suffer vitamin deficiencies and may be treated by vitamin supplementation. It would therefore have been obvious to one having ordinary skill in the art to have added water soluble vitamins and/or folic acid in combination with each other or in combination with vitamin C or carnitine, since dialysis patients are known to suffer from deficiencies of these nutrients. Furthermore, it would have been obvious to one having ordinary skill in the art to have added other nutrients, such as iron or zinc, in appropriate forms, to such dialysis solution since these nutrients are also known to be decreased in patients undergoing dialysis and doing so would allow the treatment of several deficiencies at one time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

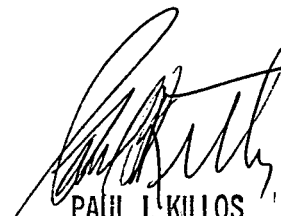
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc

November 1, 2001



PAUL J. KILLOS  
PRIMARY EXAMINER